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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,018	07/15/2005	Brian Strong	CCS 0211 USNP	3198
27777	7590	12/04/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1618	
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			12/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,018	Applicant(s) STRONG ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/21/04 was filed on the mailing date of the Specification on 12/21/04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al (USPN 6,254,887 hereafter '887). The claims are drawn to a process for manufacturing spherical pellets comprising mixing a water-soluble drug, a spheronizing agent and a lubricant, extruding the resultant mixture and spheronizing the extrudate to form a pellet.

The '887 patent teaches a method of making a spherical pellet comprising combining tramadol (a water soluble drug) a spheronizing agent such as microcrystalline cellulose (col. 4, lin. 28-35) and a lubricant such as fatty acid esters (col. 3, lin. 55-64). The ingredients are combined, extruded together and spheronized to form spherical pellets (col. 5, lin. 12-20). These pellets are coated with a controlled release polymer composition (examples). The tramadol is present in a concentration from about 20-70 % (col. 6, lin. 25-28) while the microcrystalline cellulose is present in an amount from 10-90% (*Ibid.*). The glycerol fatty acids are present in an

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amount up to 60% (col. 3, lin. 55-63, examples). Tramadol is the active agent used in the spherical pellet and the compound inherently has water solubility greater than 0.5 g/ml. A small amount of water is present during the mixing process yet is removed during processing so that resulting pellet has low water content (examples). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Miller et al (USPN 6,254,887 hereafter '887) in view of Bartholomaeus et al (USPN 6,576,260 hereafter '260). The claims are drawn to a process of making spherical pellets where the pellets are filled into a capsule.

As discussed above the '887 patent discloses a method of making pellets comprising combining tramadol, a spheronizing agent, and a lubricant, extruding the mixture and

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spheronizing the extrudate in order to form spherical pellets. The patent discloses that the dosage form can be any oral form including tablets yet is silent to the tablets being filed with the pellets of the patent. Filing a hard or soft capsule with pellets formed from spheronization is well known in the art and would have been an obvious modification of the prior art as shown in the '260 patent.

The '260 patent discloses an oral tramadol formulation comprising coated dosage forms (abstract). The coated dosage forms can be pellets formed by extrusion followed by spheronization for shaping (col. 3, lin. 32-40). The pellets can be filled into the capsules and administered orally (col. 2, lin. 45-56). It would have been obvious to fill the pellets of the '887 patent into capsule as disclosed in the '260 patent in order to deliver more active agent to a patient.

With these things in mind it would have been obvious to fill the pellets of the '887 patent into capsules as disclosed in the '260 patent in order to deliver more active agent to the patient with greater ease. Further both patents teach a similar formulation comprising tramadol, cellulose spheronizing agents and lubricants. The '260 patent establishes the level of skill in the art regarding the filling of capsules with preformed pellets. It would have been obvious to combine the prior art in such a way with an expected result of a stable oral dosage form useful in treating pain.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-

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0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618